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TRANSCRIPT

Mr. Kraut I would love to start the full council meeting, but first, Mr. Holt, would you like to do the Special Codes Committee?

Mr. Holt Thank you, Mr. Kraut.

Mr. Holt My name is Tom Holt. I'm the Chair of the Committee on Codes, Regulations and Legislation. I have the privilege to call to order the Codes Committee meeting and welcome members, participants and observers. I'd like to remind the council members, staff and the audience that this meeting is subject to the Open Meeting Law and is broadcast over the internet. The webcast is accessed at the Department of Health's website and the on-demand webcast will be available no later than seven days after the meeting for a minimum of thirty days and then a copy will be retained by the department for four months. Some suggestions to follow to make this meeting successful. Because there is synchronized captioning, it's important that people do not talk over each other. Captioning cannot be done correctly with two people speaking at the same time. The first time you speak, please state your name and briefly identify yourself as a council member or DOH staff. This will be of assistance to the broadcasting company who's recording this meeting. Please note that the microphones are hot, meaning that they will pick up every sound and I therefore ask that you avoid rustling papers next to the microphone and also be sensitive about personal conversations or sidebars as the microphones will pick up this chatter. A reminder for our audience. There's a form that needs to be filled out prior to you entering the meeting room, which records your attendance at this meeting. It's required by the Commission on Ethics, Lobbying and Government and in accordance with Executive Law 166. The forms also posted on the Department of Health's website under Certificate of Need. In the future, you can fill it out prior to council meetings. Thank you for your cooperation in fulfilling our duties as prescribed by the law. This morning we have three items on the agenda. We have one for adoption and two for discussion. The first for adoption is adding mpox virus to the list of sexually transmitted diseases.

Mr. Holt Can I have a motion for a recommendation of adoption of this regulation to the full Public Health and Health Planning Council?

Mr. Holt Dr. Watkins, thank you.

Mr. Holt Mr. Travis O'Donnell and Jason Riegert from the department are available and will provide us with information on this proposal.

Mr. O'Donnell Good morning, everyone. Can you confirm that you can hear me?

Mr. Holt Yes.

Mr. O'Donnell Thank you.

Mr. O'Donnell Pleasure to be with you today.

Mr. O'Donnell The Department of Health is proposing the permanent adoption of regulations amending Title 10 of the New York Codes, Rules and Regulations, Section 23.1, adding mpox to the list of diseases officially recognized by New York State as sexually transmitted diseases. As a reminder, this council originally approved this action via emergency regulation on October 6th,2022, and extended it on December 8th. As background, I want to remind you of our intent with this regulation. If you'll recall, during the height of the outbreak in New York State, the department was receiving reports that adolescents who were placed at high risk for infection were unable to have access to vaccination and testing due to the provision that requires parental consent for most communicable disease services. The purpose of this regulation was to ensure that adolescents under the age of 18 were allowed to consent to their own vaccination and testing, which is permitted absent parental consent for conditions that are recognized as STDs in New York State. Since the outbreak has peaked nationally and here in New York State, cases have really plummeted. As of January 25th, the seven-day rolling average number of cases nationally was just three. That's a huge public health achievement. While it’s great news, we know from previous outbreaks and experience from other STIs, especially syphilis, that during periods of time when cases are low, you know, these are really recognized as critical points to continue prevention efforts, especially vaccination when we have it to ensure that STDs don't recur and resurge. We are seeking permanent adoption now to enshrined in law the ability of minors to receive their own testing and vaccination to prevent against future potential outbreaks. This desire is really part of a broader effort on the part of the department to normalize and testing, treatment and vaccination underneath the sexual health umbrella and taking steps to incorporate these services into normal STD clinic operations. We do have some data to suggest that our policy goal of ensuring access for minors has been at least partially successful. After the passage of the initial emergency regulation on October 6th, the average weekly number of people under the age of 18 being vaccinated has remained relatively stable. While the number of vaccinations among all other age groups combined has decreased significantly by about 300%. Since the emergency regulation was enacted, the department has completed the assessment of public comment process, which is required of all permanent rulemaking. That period, that assessment period ended on December 27th. During the course of this assessment of public comment process, the department received one public comment from the New York State Association of County Health Officials. Supportive of permanent adoption. Importantly, the department has received no additional anecdotal reports of adolescents being unable to access mpox vaccinations since the emergency regulation went into place. Thank you for the opportunity to put forth this regulation for approval. I look forward to your questions.

Mr. Holt Thank you, Mr. O'Donnell.

Mr. Holt Questions from the members of the committee or the council?

Mr. Holt I'm not seeing any here in Albany.

Mr. Holt Jeff, anything there in New York?

Mr. Kraut No, there are none.

Mr. Holt No comments from the community.

Mr. Holt All in favor?

All Aye.

Mr. Holt Any opposed?

Mr. Holt That motion carries.

Mr. Holt This regulation will now go to the full council for its adoption.

Mr. Holt Next, we have for discussion clinical staffing in general hospitals. This regulation is being presented to the committee for discussion only and will be presented to the committee in the full Public Health and Health Planning Council in an adoption for the later date.

Ms. Sheltry Good morning. This is Jacqueline Sheltry from the Department of Health. I'm going to comment on the ICU critical care unit staffing regulations. First, I want to note that these regulations are intended to implement two separate statutory requirements pursuant to Public Health Law, Section 2805T, Subdivisions 5 and 17. Those subdivisions first state that the clinical staffing plan that hospitals develop must, among other things, comply with staffing, intensive care and critical care units pursuant to regulations promulgated by the Department of Health. The second component of this underlying statute is Subdivision 17 requires the disclosure of certain nursing quality indicators and provides that the Commissioner of Health shall promulgate rules and regulations on the disclosure of those nursing quality indicators. Specifically, regarding information regarding nursing, staffing and patient outcomes. Turning to the context of the regulations themselves, the first substantial change since these regulations were originally presented is to add a new Section 400.25 Subdivision G. This new subdivision implements the nursing quality indicator reporting requirements that I just mentioned at Public Health Law 2805T 17. Specifically, this new subdivision requires general hospitals to electronically file with the Department, the General Hospital Clinical Staffing Plan Template. That is a prescribed form that the department will issue. The template is intended to achieve the statutory goals of allowing patients as well as the public to clearly understand and compare staffing patterns and actual levels of staffing across facilities. The second substantial change to the regulations since these regulations were initially presented before this committee in Section 405.5 is to add a new paragraph A1, which requires the Director of Nursing Service to develop a nursing service plan which regards the number and types of nursing care for all hospital areas. That must be in accordance with the hospital approved clinical staffing plan. I want to briefly note that this is actually a slight change from the regulations that were originally sent to this committee about a week ago. Based on initial conversations with members of this committee, we realized that there may be concerns with the word implement as written in the regulations that are in the package before you. We've therefore revised paragraph A1 to state, and I'll quote here, the Director of Nursing Service shall be responsible for the operation of the service, including developing such nursing service plan to be approved by the hospital for determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital in accordance with the hospital clinical staffing plan, as provided in Paragraph 8. In other words, this is really taking the preexisting authority for the preexisting directive, I should say, for the Director of Nursing service to develop a nursing service plan and putting that within the context of the hospital greater clinical staffing plan. In other words, a conforming change. The next substantial change is to add at Paragraph A8 within this same section of the regulation. This section first requires general hospitals to establish and maintain a statutorily required clinical staffing committee. The committee is responsible for

developing and overseeing the implementation of the annual hospital clinical staffing plan I just mentioned. In accordance with the underlying statute, this clinical staffing plan for the regulations must delineate intensive care and critical care units of the hospital, include specific staffing for each patient care unit and work shift based on the needs of patients and include specific guidelines or ratios, matrices or grids indicating how many patients are assigned to each registered nurse and the number of nurses and ancillary nursing personnel to be present on each unit and shift. Again, that is mirroring the statutory language. Likewise mirroring the statutory language, again, the regulations specify that the clinical staffing plan was due originally to the Department of Health by July 1st of 2022 and must be submitted in July annually thereafter. It also specifies that beginning January 1st, 2023, and annually thereafter, each hospital shall implement the clinical staffing plan that was adopted in July of the prior year. Just to reiterate, those dates come from the statute as well. Finally, the Section at A8 sets forth a non-exhaustive list of factors to be considered and included in the hospital clinical staffing plan. These factors mirror the factors set forth in the statute. Third, the next substantial change to the regulation are amendments to Section 405.22 regarding critical care and special care services. This is the crux of the amendments pursuant to the statutory Directive at 2805T to promulgate regulations regarding ICU and CCU staffing. In particular, this section sets forth a minimum one to two nurses to patient ratio for intensive care and critical care patients. I want to emphasize based on the needs of the patients, not the unit they are in. Therefore, this section requires the attending practitioner to determine whether the patient should be defined as requiring critical care or intensive care. Specifically, the one to two ratio applies per the regulations whenever the attending practitioner determines that the condition and medical needs of the patient require admission to an intensive care or critical care unit and considers the continued need for that level of care based on ongoing assessments. Again, this regulation, this portion of the regulation emphasizes that the determination is based on that attending practitioner and not solely based on where the patient is in their location of the hospital. The regulation further sets forth two exceptions to these one to two nurses to patient ratio. First, continuing the theme of being based on the particular needs of the patient, the exception reads, if the attending practitioner determines that the patient in the ICU or CCU no longer requires intensive or critical care, or the patient is awaiting transfer to a lower level of care, the one to two ratio would not apply. The second exception spelled out in the regulations is that a patient placed in the ICU or CCU because an acute care or other inpatient service bed is not available, and the attending practitioner determines that intensive or critical care is not required the one to two ratio would not apply. Finally, the section at A8 sets forth those complaints for violations of the one to two ratio shall first be made to the hospital's clinical staffing committee, and that's pursuant to the statute, which directs that the Clinical Staffing Committee be the first to attempt to resolve complaints. The regulations then states that complaints can also be made to the Department of Health if the Clinical Staffing Committee has not resolved the complaint after 90 days. I want to point out that this is actually a second change from the package of regulations that's before this committee member from last week. We realized there was invariably the word or included in this provision which could have been read to indicate that the Department of Health would look at complaints that weren't previously deemed unresolved by the clinical staff in committee. There's going to be a technical change to that portion of the regulations. I'll just briefly mentioned that there are other conforming changes made to the regulation. There's six of them basically to bring preexisting regulations regarding staffing requirements in other areas of the hospital in line with the clinical staffing plan. These regulations pertain to operating room, emergency room, perinatal services, pediatric intensive care units, burn unit staffing and living donor transplantation services. All of those six sections of existing regulations are merely amended to state that the staffing plans

must be in accordance with the hospital's overarching clinical staffing plan. I will end there and turn it over to questions from the committee members.

Mr. Holt Thank you.

Mr. Holt Are there questions from the members of the committee or the council?

Mr. Holt Dr. Soffel.

Dr. Soffel My name is Denise Soffel. I am a member of the council and of the Codes Committee. I guess I'm trying to understand, what is the problem that we are trying to solve? I find it hard to believe, although maybe it's because I'm not a clinician, that we often have people who require ICU level services who are not actually in an ICU just because of the equipment involved in that level of intensity of care. I'm imagining that the problem is more in the converse that we have people who are in ICU because there's no place to move them out to. Do we have any idea how frequently that arises and how large a problem this is that we are addressing?

Ms. Sheltry I'll welcome other input from members of our hospital division who may want to comment on the specific aspect of the data part of your question.

Mr. Kraut We have clinicians on the council that might be able to give very firsthand experience in addition to the hospital folks, but it's a very common occurrence.

Ms. Sheltry Thank you, Mr. Kraut.

Ms. Sheltry I would just like to add in terms of to specifically address your question of the problem we're trying to solve. I want to highlight that these regulations are implemented pursuant to statutory directives. That's the initial impetus of doing these regulations, of course, as well as the fact that I'll note pursuant to the regulatory text that we're looking at the needs of the patients. Regardless of whether or not this is a common problem, we really want to assess patients specific needs to determine whether or not they're subject to the one to two patient ratio. There is some flexibility, so to speak, built into the regulations. I welcome comments both from the members as well as my colleagues.

Mr. Kraut Could we just ask Dr. Kalkut, I think, might have some insight to share with Denise.

Dr. Kalkut To answer the question, I think it is common throughout systems and is addressed as needed and often on a daily basis. We must open up beds for people who clearly require that level of care.

Mr. Holt Thank you.

Mr. Holt Looking for other questions.

Mr. Holt Jeff, we have another question or comment here in Albany.

Dr. Morley Thank you, Mr. Chairman.

Dr. Morley Just to add on to what Dr. Kalkut said, and for your understanding. When a patient is identified as they can leave the ICU, it virtually never happens that they leave

within the hour. It is incredibly common that they're there for hours waiting for somebody upstairs to first go home and then be admitted. We're just talking about the patients that are ready to go out. There are other patients, it is more extensive than that, for sure, but that's just for your understanding to give you an easy example of somebody waiting for hours for somebody to vacate a bed upstairs.

Mr. Holt Thank you.

Mr. Holt Ms. Soto in New York.

Ms. Soto I have like a two part question. Who in the department or agency oversees the compliance reports? Secondly, if a hospital does not meet those compliance or the staffing, what action is taken?

Ms. Sheltry This is Jacqueline Sheltry. Again, we have a division of hospitals and diagnostic and treatment centers, which are our surveillance arm for hospitals and diagnostic and treatment centers that would be overseeing compliance with the statute, as well as these regulations, with the caveat that, as I as I explained before, if there is complaints about the ratio and compliance with the clinical staffing plan as implemented by the hospital, those must originally go to the hospital clinical staffing committee before they come to the Department of Health. It gives the hospital a chance to resolve the dispute first. Overall, it is within the Department of Health.

Mr. Holt Thank you.

Ms. Soto If they don't meet, even with hearing the opportunity to explain or update the situation. Is any action taken?

Ms. Sheltry Well, first of all I'll say if the complaint in issue is unresolved, first by the hospital Clinical Staffing Committee, our hospital surveillance team would look at the underlying complaint. For instance, if there's any patient harm, the severity of that complaint in order to assess whether or not a corrective action plan is necessary. Essentially, we work on a case-by-case hospital specific level to determine what the corrective action plan must be, if any, must be implemented and or whether penalties must be assessed, again, depending on the exact facts presented and in other circumstances necessary for the department to look at. That's all basically a work in progress based on the specific needs of the hospital and the specific facts presented in the complaint.

Mr. Holt As a reminder, this was on the agenda for discussion and therefore, will be coming back to us at a future meeting.

Mr. Holt Next up for discussion, we have perinatal services, perinatal regionalization, birthing centers and maternity birthing centers. This regulation is being presented to this committee for discussion only and will be presented to the committee in the full Public Health and Health Planning Council for Adoption at a later date. Ben Wise and Jacqueline Sheltry from the Department are available and will provide us with information on this proposal.

Mr. Wise Good morning, everyone. My name is Ben Wise. I'm a Associate Director with the Bureau of Perinatal Reproductive and Sexual Health within the Division of Family Health. We have put together a regulatory package that addresses parts 12.2, 405.21 and sections 721, 754 and 795, which cover the aforementioned parts of regulation.

Mr. Kraut Could you move the mic closer to you?

Mr. Wise Sure.

Mr. Wise Is this better?

Mr. Kraut Thank you.

Mr. Wise The regulatory package is over 130 pages. Rather than going through it in detail, I'm going to be giving a bird's eye view of the background and the major changes for this regulatory package. Just for level setting, perinatal regionalization is a comprehensive and coordinated, geographically structured system of care organized around a series of regional perinatal centers or RPCs, each of which supports and provides clinical expertise, education and quality improvement support to a group of affiliate birthing hospitals and birth centers. The objective of perinatal regionalization is to improve the quality of care for all pregnant and postpartum people and newborns in New York State, at the birthing centers and birth hospitals in accordance with current standards for perinatal care. The regulation changes were made following input and recommendations developed from an expert panel of approximately 50 multidisciplinary clinical providers per hospital and clinical organizations across the state and from the fields of midwifery, nursing, obstetrics, pediatrics and subspecialty providers. Additional input was sought through expert panel subcommittees and through ad hoc communications outside of the expert panel as necessary, such as insurance discussions. For parts 12.2 and 405.21, the purpose of the updates is to update the regulations in alignment with current standards of practice. For example, this includes removing references to specific procedures or treatments that may have changed over time. We also intended in the update to allow flexibility for the wide variety of clinical circumstances that can happen during pregnancy, childbirth and the postpartum period. Finally, we look to balance between establishing regulatory requirements while supporting clinical practice and patient centered care. For Section 721, again, we are updating the regulations to match with current standards of practice, as well as updating the system to incorporate freestanding and midwifery birth centers. This includes requiring the RPCs to establish affiliation agreements and provide similar supports as they do for affiliate birthing hospitals. Additionally, it requires birth centers to engage with the RPC and other affiliate hospitals in quality improvement, the timely transfer and clinical consultation. Additionally, we have added the Chief of Midwifery Services as a part of the birthing hospital leadership team when a hospital employs midwives. Finally, we have made updates to the requirements for ancillary services, including new sections for the linkage to alcohol and substance use treatment as well as mental and behavioral health services. The remaining ancillary services are also revised to align with current standards of care. Finally, there are some updates and clarifications to the transfer agreement and affiliation agreement between the RPC and their affiliate birth center and birth hospital. For both freestanding and midwifery birth centers, the changes, again, highlight meeting up with current standards of practice, as well as incorporating the affiliation and transfer requirements, quality improvement participation and overall implement integration with the perinatal regionalization system. We have also removed the advanced cardiac life support requirement that is currently in regulation for the birth center attendant, as this creates a dichotomy between the available services and expertise at a birth center that doesn't have a team compared to even a level one birthing center that does have a team. The same changes have been made to midwifery birth centers. I will turn it over to Jackie to discuss the accreditation and establishment changes.

Ms. Sheltry Thank you, Ben.

Ms. Sheltry As Mr. Weiss explained during his presentation, these regulations overall contain comprehensive revisions to the perinatal regionalization regulations to add midwifery birth centers to the structure of care for the lowest risk pregnancies. As Ben just mentioned, the crux of my presentation is going to focus on specific amendments to Part 795 that sections 795.11 and 795.12 to amend the existing midwifery birth center regulations that were promulgated in 2019 to bring those regulations in line with the Midwifery Accreditation Act of 2022. As the members may know, this act amended the public health law and Section 2803 11 to add new criteria regarding the Department's Certificate of Need process for review of midwifery birth centers and to provide that accreditation by a recognized accreditation organization can serve as evidence of meeting the requirements for a certificate of incorporation, articles of organization and establishment, but it does not substitute for certificate of need review and approval. Specifically, the statute directs the midwifery birth centers must include a character and competence review, demonstrate that the proposed MBC operator meets establishment requirements under existing law, evidence the capability to fund any acquisition renovations or construction costs and finally demonstrate that the premises and equipment comply with the required life and safety building standards necessary to protect the life, safety and welfare of patients and staff. The core of the amendments to Section 795.11 and 795.12 principally deal with that ladder. The fourth prong to ensure that the midwifery birth centers before approval for establishment do comply with required life and safety and building standards. As I mentioned before, I'm going to concentrate on section 795.11 and 795.12. If any members following my presentation have specific questions about other parts of 795, I'd be happy to answer them, but I believe Mr. Wise covered them for the most part in his presentation. Section 795.11 is repeal and replace language for that existing section and concerns midwifery, birth center, operational standards and accreditation. First, under this section it requires that midwifery birth centers comply with existing regulations in part 400, which apply to medical facilities generally. Specifically, sections 400.2 through 400.7. These set forth minimum standards for medical facilities, such as requirements for identification of facility personnel with badges, inspection and reporting requirements and transfer agreements. Additionally, it requires compliance with pre-existing sections of regulation at section 751.5 through 751.10 relating to certain diagnostic and treatment center standards. For example, standards regarding medical record retention and development of operating procedure requirements. More specifically for midwifery birth centers, the regulations provide that in addition to those aforementioned medical facility operating requirements, midwifery birth centers must have affiliation agreements with designated regional perinatal centers, as Mr. Wise explained. Patient transfer agreements with those facilities and other designated birthing hospitals and the implementation of quality improvement protocols. The section in accordance with the Midwifery Accreditation Act further clarifies the effect of the role of national accreditation if the midwifery birth center is seeking one or plans to seek it. These regulations state that the department may at its sole discretion accept proof of accreditation as evidence of both the intent and capability to comply with minimum operational standards or ongoing compliance with minimum operation standards. The department must first determine that the accrediting body has sufficient standards in order to substitute for those existing operational standard requirements. The section of the regulation further provides regarding accreditation that the department may use an accrediting agencies survey in lieu of a survey by the department for facility inspection. It also states that the list of accreditation agencies with which the department has a collaborative agreement in order to use their survey in lieu of a department survey will be posted on the department's website for awareness of midwifery birth centers. Likewise, the regulations state that an accreditation

agency may at the department's discretion investigate complaints on its own that are received by the department related to the care and services provided by a midwifery birth center. Notwithstanding these provisions, the department may elect to survey the midwifery birth center on its own utilizing evidence-based standards of care in operation. The regulations further provide that survey reports for midwifery birth centers as well as complaints, except where disclosure of certain provisions are prohibited by law are subject to public disclosure. Finally, the regulations provide that the midwifery birth center must notify the department within seven days of failing to gain accreditation or be re accredited or losing accreditation. The second substantial change to these regulations, again in accordance with the Midwifery Accreditation Act, is to Section 795.12. This section provides first that applications for establishment must be submitted electronically through as other certificate of need applications are. Further requires that an application for establishment contained four essential components of information; the projected number of births over time, the character and competence of the proposed incorporators, members, partners or operators, the applicant's ability to fund any acquisition, renovations or construction costs and the fitness and adequacy of premises and equipment to be used. Turning to that last factor regarding the fitness and adequacy of premises and equipment. These regulations specify that in general, the department will assess compliance with the Facility Guidelines Institute or FGI Standards for birth Centers and ADA compliance. More specifically, per the regulations, it states that in assessing whether or not the facility meets adequacy for premises and equipment standards, the department will first assess existing regulations at part 711, which are general standards for construction for all Article 28 facilities. They set forth multiple sections of ADA and ventilation standards per and ANSI that would apply. Additionally, the regulations critically state that compliance Life and Safety Code 101 for new or existing business. Occupancies would only apply if the birth center is occupied by fewer than four patients at any time, not including infants. Additionally, the regulations specify that the FGI standards or Facility Guideline Institute guidelines that will apply are the guidelines specific to requirements for birth centers as well as ADA compliance for standards for accessible design. Finally, the law states that where provision of these laws conflicts with a local law or ordinance, the most stringent standard would apply. Also critically, this section of law sets forth additional flexibility for the assessment of operational standards for limited midwifery birth centers. These are birth centers that have three or fewer birthing rooms and six or fewer rooms total. That's exam rooms and birthing rooms combined. These possibilities are set forth in the regulation due to the very limited size of these birth centers. Specifically, the regulations allow these limited sized midwifery birth centers to meet the following less stringent standards. There's no waiting room required. No staff lounge required. There may be a shared staff and public toilet room. There's a reduced number of electrical receptacles. Minimum quarter WIS are reduced to 36 inches. Exam rooms may be a minimum of 80 square feet or in some cases 72 square feet. The environmental services room may be shared with other business occupant tenants on the same floor to store cleaning equipment and ventilation standards under Standard 170 would not be required. Finally, as an additional flexibility to midwifery birth center applicants, both the limited size and general midwifery birth center applicants, their accreditation act specifies that where an applicant is unable to meet a requirement in this paragraph, the application must include a detailed explanation as to why they cannot meet that standard for the department and the council's consideration. That language was added principally in accordance with the Midwifery Accreditation Act's directive that the department harmonies existing midwifery standards pursuant to accreditation organizations as well as existing con requirements. It essentially codifies and regulation that harmonization standard. I'll stop there. I welcome questions for Mr. Wise and myself.

Mr. Holt Thank you.

Mr. Holt Questions here at Albany first and then down to New York.

Mr. Holt Any questions here in Albany?

Mr. Holt Jeff, anything there in New York in terms of questions?

Mr. Kraut Yes, Ms. Soto.

Ms. Soto My question is more process. This is listed as for a discussion. When does it come up for, you know, in length of time the process for adoption?

Ms. Sheltry This is Jacqueline Sheltry. The regulations are listed as for discussion. The intention is that shortly after this meeting we'll file in the state register. We're looking at probably around mid-February, they'll be published for a 60-day public comment period. After the department assesses those public comments if there's no substantial changes, we would publish for final adoption. That would probably be sometime in April to May, depending on how many public comments we would receive and again, whether or not substantial changes are required. As I believe Mr. Holt mentioned earlier, the regulations would come before the committee again for adoption.

Mr. Kraut We have a question from Dr. Lim.

Dr. Lim Sabina Lim, council member. This is actually a comment about an existing section of the regulation. It has to do with the administration of vitamin K and Erythromycin prophylaxis. I think a number of hospital providers have unfortunately been experiencing some challenges in implementing this. There have been a lot of reluctance by small numbers of parents, despite extensive outreach and education about the importance of vitamin K. I'm not saying that that's extremely important, but I think it puts providers in this sort of untenable double bind of what to do because of the way it's worded it shall administer. I understand that there might be a new guidance memo coming out from the DOH, so I just ask that hopefully that that guidance memo be expedited to help give some guidelines to providers for how to handle that kind of situation better, because unfortunately, it's coming up more and more frequently.

Dr. Lim Thank you.

Mr. Wise We're certainly aware of the situations, particularly with the vitamin K administration. We are working on a joint letter and that should be coming out in the coming weeks. To clarify, a previously issued joint letter specific to vitamin K, and we will continue to work with health care providers and hospitals to support education efforts and as well as addressing issues related to parent hesitancy.

Dr. Lim Thank you.

Mr. Kraut Since the regulations are going out for comment and modification, just make sure the administrative guidance that you provide is harmonized with the reg. If you need to change the wording in the reg, this would be the time to do it when you bring it back. I don't know, you know, the details, but I don't know how you're going to express it. This is your opportunity to codify it. I'll just leave it at that for you to take under consideration.

Mr. Kraut Mr. Holt, that's all the comments we see here in New York.

Mr. Holt Great.

Mr. Holt Thank you, Ms. Kraut.

Mr. Holt Dr. Soffel.

Dr. Soffel I'm sorry. There's a lot to take in here. It's taken me a while to sort of figure out what I want to understand. You say that these regulations were drafted in conversation with the national bodies, both ACOG and the National Midwifery, whatever the accreditation body is called. Are the regulations for New York consistent with those national bodies, particularly on the midwifery and birthing center side? Are they more stringent in some areas than what the national bodies are suggesting?

Ms. Sheltry Two responses to your question. That is correct. We did consult with advocates, including the accrediting bodies. The physical requirements for the regulations are the same as the Commission for the Accreditation of Birth Centers, but this is actually a point that's been raised by some of the midwifery advocacy groups we consulted with in drafting these regulations to clarify that there are some standards, I would not go so far as to say are more stringent than the accrediting bodies, but include standards that an accrediting body wouldn't necessarily look at, such as the transfer agreement, operating procedures and protocols that Mr. Wise explained during his presentation. They do go beyond the accrediting bodies, but that is because of the other requirements within health facilities under Article 28, as well as they're bringing midwifery birth centers into the regional perinatal system. There are additional ones, but just something that a accrediting agency wouldn't necessarily look at.

Ms. Sheltry Does that answer your question?

Mr. Holt Thank you.

Mr. Holt Just looking to see if there are more questions or comments here in Albany.

Mr. Kraut One more question in New York from Dr. Kalkut.

Dr. Kalkut Gary Kalkut from the council. You'd mentioned earlier that ACLS training for birthing centers staff has been dropped and certainly can understand that. I just want to make sure that other staffing is trained and what the requirement is for that. That includes pediatric module or as part of that training.

Mr. Wise Yes, BLS as well as neonatal resuscitation program training and active certification is required still, I believe, for both midwifery and freestanding birth centers. It's two staff trained in that at each birth.

Mr. Kraut Two trained individuals physically in the facility for each birth.

Mr. Wise Yes.

Mr. Kraut Okay.

Dr. Kalkut If there are four deliveries going on or two deliveries going on, there's two at each at the bedside in each?

Mr. Wise At least one would be directly attending. In the highly unlikely event that a birth center has multiple births at the same time, then we would anticipate the possibility of a quote unquote, floater who is certified in both. Because the midwifery birth centers are unlikely to have eight staff members, for example.

Dr. Kalkut The problem is the highly unlikely is what causes problems in a lot of circumstances. The floater seems suboptimal to me in that circumstance.

Mr. Kraut Maybe during the public comment period, that's something that others will bring up that should be taken into consideration. I would just flag that issue for us when you bring it back just to discuss what was the resolution of that.

Dr. Kalkut Certainly.

Mr. Kraut That's it in New York.

Mr. Holt Thank you.

Mr. Holt Seeing nothing else here in Albany, again, thank you for that helpful discussion. I think it gives the department and other providers in the community some additional direction as we go forward. Again, this was for discussion, and we'll be coming back to the full council at a future date, as you heard.

Mr. Holt That concludes this morning's committee meeting on Codes, Regulations and Legislation.